

### **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 8-19 will be pending in the application subsequent to entry of this Amendment.

Please take note of the Information Disclosure Statement filed concurrently herewith providing English abstracts of JP 07-126604 and DE4444137.

#### **Discussion of Amendments to the Claims**

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention, to respond to the examiner's comments and rejections on page 3 of the Official Action relating to claim clarity and to direct the claims to preferred embodiments of the invention. The relationship between the originally filed claims and the new claims presented above is as follow:

Claims at the Office Action	1	2	3	4	4	5	6	
New claims	8	9	8	10	11	8	15	
Claims at the Office Action	7	-	-	-	-	-	-	-
New claims	12	13	14	15	16	17	18	19

New claim 8 is a combination of original claims 1, 3 and 5. Basis for new claims 13 and 14 is in page 5, lines 17-21; the support of new claim 16 is in page 8, line 20 to page 9, line 25; the support of new claim 17 is in page 9, line 26-32; the support of new claim 18 is in page 13, line 18-23; and the support of new claim 19 is in page 14, line 24 to page 15, line 11. As the new and amended claims find basis in the description, no subject matter has been added.

The examiner questions the form of expression used in original claim 3 the subject matter of which is now incorporated into new claim 8. To illustrate the claim in a different format:

New claim 8 reads (in a revised format to emphasize the comments that follow):

A water-in-oil emulsion preparation for external use on the skin, wherein the oil phase comprises a mixture of an ester compound obtained by esterifying the following ingredients (A), (B) and (C), (A) a polyhydric alcohol, (B) a fatty acid and/or hydroxy fatty acid each having 8 to 30 carbon atoms and (C) a dibasic carboxylic acid having 12 to 30 carbon atoms, ;

an ester oil;

a surfactant; and

an oil other than ester oil, and

that the aqueous phase comprises an aqueous solution of a water-soluble inorganic salt:

in which preparation, the compounding amounts of the respective ingredients in

the **oil phase** are such that, based on the total mass of the ester compound, the ester oil, the surfactant and the oil other than ester oil, the compounding amount of the ester compound is 0.1 to 30 % by mass, that of the ester oil is 1 to 99 % by mass, that of the surfactant is 0.01 to 40 % by mass and that of the oil other than ester oil is 0.01 to 98 % by mass;

the compounding amount of the water-soluble inorganic salt in the **aqueous phase** is 0.01 to 10 % by mass, based on the total mass of the water-soluble inorganic salt and water; and

the ratio by mass of the **oil phase** to the **aqueous phase** is 10:90 to 90:10.

From the above formatting/rearrangement it will be noted that the two phases are separately described, first the oil phase then the aqueous phase and finally the relationship between the ratio by mass of the oil phase to the aqueous phase. From this one will be able to quickly see the basis for the calculation of the amounts of the various components.

As to original claim 7 which now appears as new claim 12, the examiner's comment bridging pages 2 and 3 of the Official Action has been noted and adopted.

For the above reasons it is respectfully submitted that claims 8-19 are in proper formal order and compliant with 35 USC §112, second paragraph and that the amendments made to the claims and the new claims added do not include new matter. Reconsideration and withdrawal of this rejection directed primarily to original claims 3 and 7 is requested.

Response to Provisional Non-Statutory Obviousness-Type Double Patenting Rejection

The originally filed claims in this application are the subject of a provisional non-statutory obviousness-type double patenting rejection over claims 1-14 of copending application 10/575,260 published as U.S. 2007/0264207. This copending application is assigned to the same assignee as the present application but is being handled by another legal representative.

The provisional rejection states: "Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/575,260 in view of EP 1044672. Although the conflicting claims are not identical, they are not patentably distinct from each other because while copending claim 1 does not require an inorganic salt, this is required by copending claim 8. Further, while the copending claims do not specifically recite W/O emulsion, they have all of the same ingredients as instant claims. "

Applicants disagree and believe there is a misunderstanding of the invention of the original claim 1 (now new claim 8) of the present application (hereinafter referred to as the present invention) and that of the 260 application and this misunderstanding has resulted in an incorrect conclusion.

The 260 invention is an invention containing as necessary constituents (1) a specific ester compound, (2) an ester oil and (3) an ultraviolet protective powder, whereas the present invention is an invention containing as indispensable constituents (1) a specific ester compound, (2) an ester oil, (3) a surfactant, (4) an oil other than an ester oil and (5) an water-soluble inorganic salt. The water-soluble inorganic salt is not a constituent in all the claims of the 260 application, and the ultraviolet protective powder is not a constituent in all the claims of the present application, and, therefore, both inventions are patentably distinct from each other.

Moreover, both inventions are utterly different from each other in problems to be solved by the invention and effect of the invention.

The problem to be solved by the invention with respect to the 260 invention is as follows, as described in paragraphs [0005]-[0006] and [0020]. Namely, ultraviolet protective powder is often commercially sold in a dispersed state in water or an oil. But, there has been a problem that the powder precipitates with time lapse. But, when the viscosity of such a dispersion is raised so as to inhibit this, the handling properties deteriorate and dispersibility into cosmetics also

decreases, and, thus, the ability of the ultraviolet protective powder cannot be displayed, and, moreover, there arises a possibility that the stability of the cosmetics is affected. This invention aims to reconcile the stability and handling properties of a preparation in which an ultraviolet protective powder is dispersed. This reconciliation effect is demonstrated in the examples, particularly in Table 12.

On the other hand, the problem to be solved by the present invention is as described in page 1, line 27-page 3, line 10, etc. and page 4, lines 3-6. Namely, a water-in-oil emulsion using mainly a hydrocarbon oil such as petrolatum as an oil has excellent moisture-confining properties, but poor in stability and use touch. On the other hand, an ester oil is good in use touch but not satisfactory in its moisture-confining properties. The present invention aims to provide a water-in-oil emulsion preparation for external use on the skin satisfying all of the stability, use touch and moisture-confining properties. The present preparation is satisfactory in all of stability, use touch and moisture-confining properties (page 34, lines 19-26). The effect of the present invention is demonstrated in Examples, particularly in Table 5.

Thus, both inventions are utterly different from each other in the problems to be solved by the invention and the effect of the invention, and, therefore, they are patentably completely distinct from each other.

The "inorganic salt" referred to at page 2, last line of the Action, is not properly identified or characterized. Although the Examiner says "Although the conflicting claims are not identical, they are not patentably distinct from each other because while copending claim 1 does not require an inorganic salt, this is required by copending claim 8. ", none of titanium dioxide, iron-containing titanium dioxide and zinc oxide in claim 8 of the 260 application is an inorganic salt nor is it water-soluble, and, thus, none of them fall within the definition of the water-soluble inorganic salt in the original claim 1 (new claim 8). Also from this point as well, both inventions are patentably distinctly distinguished from each other. Withdrawal of this provisional rejection is in order.

Response to Rejection Under 35 USC §103(a) of "Obviousness"

Original claims 1-7 stand rejected as being unpatentable over JP 10-273433 or "the '433 reference" in view of published European application EP 1 044 672. The presumption made by the examiner on page 4 of common ownership at the time the inventions were made is correct.

Counsel notes that the examiner has provided an English translation of Tables 2, 3 and 4 of the '433 reference. The translation of the '433 reference is a computer translation and contains or may contain errors. In the remarks that follow a human translation of paragraph [0006] is used and it is as follows:

"[0006] The present inventors have made an intense study for solving the above problems, and, as a result, they have found that when an ester compound is incorporated, it becomes possible to incorporate an ultraviolet absorber having a high polarity stably and in a high content, and a sunscreen cosmetic can be obtained which protects the skin from ultraviolet rays, inhibits occurrence of inflammation of the skin by ultraviolet rays, and, further, is excellent in use touch can be obtained, and completed this invention."

Applicants traverse the rejection as it is based upon conjecture; each of the references is complete unto itself and fully acceptable, stable, long-lasting products are produced as the references themselves state. As they are complete unto themselves there is no reason why one would need to improve either of the formulations or disclosures.

The examiner sees an apparent "need" to remove an ingredient from one and use it in the other or vice versa when in fact there is no need nor is there any reason why one skilled in the art would seek to improve either formulation, at least based upon the content of the applied references once considered in their entirety.

An objective of the '433 reference is that when an ester compound is incorporated, it becomes possible to incorporate an ultraviolet absorber having a high polarity stably and in a high content, and, further, a sunscreen cosmetic excellent in "use touch" (skin feel, smoothness, non-sticky) can be obtained. Further, in the Example, it is described that the sunscreen cosmetics of the invention of the '433 reference are excellent in stability under preservation (paragraphs [0026], [0030] (Table 3) and [0032]) is described in paragraph [0008], etc. of the '672 reference, the object of this invention is to provide a water-in-oil emulsion cosmetic wherein a large amount of water can be incorporated, and which has excellent stability over time and, further,

excellent usability (touch). Thus, at least as to stability over time and use touch of cosmetic, the objects and/or effects of both inventions of the cited documents are the same or common.

The inorganic salt in the '672 reference which overlaps in content with the water-soluble inorganic salt in the present invention is a stabilizing ingredient for cosmetics, as described in paragraph [0041], and the ester compound in the '433 reference could also be considered as a stabilizing ingredient for cosmetics, as described in paragraphs [0006] and [0017].

As to the stability evaluation test of paragraph [0026] in the '433 reference, it is stated in paragraph [0030] (Table 3) that even after the creams, as an embodiment of the cosmetic of the '433 reference, were preserved over a term as long as 3 months in constant temperature baths of -10°C, 0°C, 25°C and 40°C, there was no change in color tone, smell, appearance and use touch (substance, smoothness, creaminess) of the tested creams. Therefore, in the '433 reference, the problem of stability over time is already solved, and there is no need or motivation in the '433 reference to further add an inorganic salt of the '672 reference as a stabilizing ingredient. In other words, one skilled in the art would have no need to add the inorganic salt as a stabilizing ingredient in the '672 reference to the cosmetic of the '433 reference already has good stability over time.

Looked at conversely, the water-in-oil emulsion cosmetic of the '672 reference contains (A) a complex wherein a higher fatty acid and an ampholytic (note: seems to be an error for amphoteric) surfactant or semi-polar surfactant are bonded through the carboxyl group of the higher fatty acid, and (B) an inorganic salt and/or an amino acid salt (paragraph [0023] and claim 1), and has the advantage that a large amount of water can be incorporated and it has excellent stability over time and good use touch (paragraph [0008]). Further the examples demonstrate that the illustrated cosmetics are excellent in stability over time and use touch. Therefore, the problems of stability over time and use touch are already solved in the '672 reference. From this viewpoint, one skilled in the art would have never felt a necessity to further incorporate an ester compound of the type disclosed in the '433 reference into the cosmetic of the '672 reference.

Thus, it is difficult to believe that even if any one of the cosmetics of the '433 reference and the '672 reference is taken as a main subject, new claim 8 of the present application is suggested based on a combination of both cited documents.

The invention of new claim 8 of the present application was made based on a finding -- not disclosed in the '433 reference -- by the present inventors that the ester compound has excellent moisture-confining properties, and, by maintaining the appropriate amounts of the ester compound, the ester oil, the surfactant, the oil other than ester oil and the water soluble inorganic salt as indispensable ingredients within the ranges recited in new claim 8, a water-in-oil emulsion preparation for external use on the skin with excellent moisture-confining properties, use touch and emulsion stability can be obtained (page 4, lines 1-20 of the specification) . In this connection, moisture-confining properties mean "such an effect that the thin film of the oil, etc. formed on the skin prevents moisture transpiring from the skin from being released into the air and retains the moisture on the skin", as explained in page 1, lines 16-19 . This is an effect different from use touch, which could be expressed, in other words, as an effect to sustain the moisture, to soften rough skin and the like (page 1, lines 19-20 and page 3, lines 2-5). It is presumed in the present invention that the water-soluble inorganic salt also contributes to these desired moisture-confining properties (page 15, lines 12-17).

When the effects of the invention of new claim 8 of the present application are specifically reviewed, for example, through Tables 2-6 in the examples, Examples 1-7 where all of the amounts of the ester compound, the ester oil, the surfactant, the oil other than ester oil and the water-soluble inorganic salt used meet the recited ranges are excellent in all of their moisture-confining properties, use touch and emulsion stability, whereas:

Comparative example 2 lacking the ester compound is inferior in all of moisture-confining properties, use touch and emulsion stability.

See also: Comparative example 4 where the amount of the ester compound does not reach the recited range (the compounding amount in the oil phase being 0.08 % by mass) and the product is inferior in moisture-confining properties and emulsion stability;

Comparative example 5 where the amount of the ester compound exceeds the recited range (the compounding amount in the oil phase being 33.7 % by mass) and the product is inferior particularly in use touch;

Comparative example 3 lacking the water-soluble inorganic salt is inferior in emulsion stability;

Comparative example 6 where the amount of the water-soluble inorganic salt does not reach the recited range (the compounding amount in the aqueous phase being 0.0075 % by mass) is inferior particularly in emulsion stability; and

Comparative example 7 where the amount of the water-soluble inorganic salt exceeds the recited range (the compounding amount in the aqueous phase being 11.1 % by mass) is inferior in use touch.

Excellent moisture-confining properties, and, further, excellent use touch and emulsion stability in good balance are attained by the invention of new claim 8 of the present application. These properties are unexpected effects not disclosed nor suggested in the '433 reference and the '672 reference.

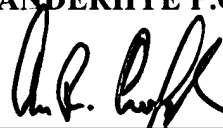
The above observations and comments have been directed to claim 8, namely that the combination of the two citations does not render obvious the claimed invention as the features of claim 8 are not fairly taught or suggested by the combined teachings of both -- and further that there is no motivation or reason to combine the documents since they are full and complete in themselves. This applies also to the dependent claims because the limitations of an independent claim are incorporated in its dependent claims. MPEP §2143.03 citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

For the above reasons it is respectfully submitted that the claims of this application as defined by the above claims are complete, compliant with 35 USC §112, second paragraph, and define subject matter that is novel and inventive over the prior art. Should the examiner require further information, please contact the undersigned.

Respectfully submitted,

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